Exactech® Octane® Elevate™ Spinal Implant System
Traditional 510(k)

510(k) Summary

APR 2 5 2014

Company: Exactech®, Inc
2320 Northwest 66th Court
Gainesville, FL 32653-1630

Date: April 21, 2014

Contact Person: Patrick Hughes
Senior Regulatory Affairs Specialist
Phone: 352-327-4762
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Proprietary Name: Exactech® Octane® Elevate™ Spinal Implant

Common Name: Intervertebral body fusion system

Classification Name:
Intervertebral Fusion Device - Lumbar (21 CFR 888.3080, Class II, Product Code MAX)

Legally Marketed Devices to Which Substantial Equivalence Is Claimed
Spinal Elements Lucent (#K071724)
Innesis PEEK Cage System (#K120464)
AccuLiF TL-PEEK Cage (#K112095 & #K123281)

Device Description
This submission proposes a new lumbar interbody fusion system. The Octane Elevate Spinal Implant is designed to provide stability during intervertebral body fusion in the lumbrosacral spine.

Indications for Use
The Octane Elevate Spinal Implant is an intervertebral body fusion device intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with Degenerative Disc Disease (DDD,) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature, and have had at least six (6) months of non-operative treatment. The device is intended for use with autogenous bone graft, and with supplemental internal fixation systems (i.e. posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems) cleared for use in the lumbosacral spine.

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Summary of Technological Characteristics
The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use**
  Proposed Octane Elevate devices and cited predicates are intended to be used with bone graft and supplemental fixation systems (i.e. posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems) for intervertebral fusion for treatment of degenerative disc disease at the levels of L2-S1.
- **Materials**
  Octane Elevate devices and cited predicate devices are made from the same PEEK-Optima and tantalum materials having demonstrable histories of safe and effective use in medical applications, per internationally recognized consensus standards.
- **Dimensions**
  Octane Elevate devices and cited predicate devices have substantially equivalent dimensions and are available in substantially equivalent size ranges.
- **Sterilization processes**
  Octane Elevate devices are provided sterile. These devices are sterilized using sterilization processes conforming to recognized industry standards.
- **Performance specifications**
  Mechanical testing results summarized in this 510(k) premarket notification demonstrate Octane Elevate devices have substantially equivalent performance characteristics compared to cited predicates based on testing per ASTM F2077 and ASTM F2267:

    - Static compression
    - Dynamic compression
    - Static compressive shear
    - Dynamic compression shear
    - Subsidence yield force

Substantial Equivalence Conclusion
The Octane Elevate Spinal Implant System is substantially equivalent to cited predicates per intended use, materials, dimensions, sterilization processes, and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 25, 2014

Exactech®, Incorporated
Mr. Patrick Hughes
Senior Regulatory Affairs Specialist
2320 Northwest 66th Court
Gainesville, Florida 32653

Re: K123607
Trade/Device Name: Exactech® Octane® Elevate™ Spinal Implant
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: April 21, 2014
Received: April 23, 2014

Dear Mr. Hughes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® Octane® Elevate™ Spinal Implant System
Traditional 510(k)

Indications for Use Statement

510(k) Number: K123607

Device Name: Exactech® Octane® Elevate™ Spinal Implant

INDICATIONS FOR USE:
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Prescription Use X **and/or** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

Please do not write below this line – use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices